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**From:** Meadows, Sarah [Meadows.Sarah@epa.gov]  
**Sent:** 12/9/2019 7:00:28 PM  
**To:** MAUNE, ONA [AG/1005] [ona.maune@bayer.com]; Mellor, Nathan [Mellor.Nathan@epa.gov]  
**CC:** Schmid, Emily [Schmid.Emily@epa.gov]; james.m.nyangulu@monsanto.com  
**Subject:** RE: EPA Reg No. 71995-AR

Hi, Ona. As soon as I receive the CRP review, I will move forward with this action. Nate let me know I should have his review this week.

Thanks,

Sarah

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**From:** MAUNE, ONA [AG/1005] <ona.maune@bayer.com>  
**Sent:** Monday, December 09, 2019 1:05 PM  
**To:** Meadows, Sarah <Meadows.Sarah@epa.gov>; Mellor, Nathan <Mellor.Nathan@epa.gov>  
**Cc:** Schmid, Emily <Schmid.Emily@epa.gov>; james.m.nyangulu@monsanto.com  
**Subject:** RE: EPA Reg No. 71995-AR

Dear Sarah and Nathan,

I'm following up on this pending action with the Agency, which is our top 71995 company number PRIA priority (originally submitted 11/2/2018). I had spoken with Nathan on 11/21, who confirmed the revised CRP self-certification referencing the new SAUE test conducted with 1.5 oz placebo (rice) was acceptable. He expected to have the amended CRP acceptance memo issued before Thanksgiving (by 11/27). As noted below, I had submitted a revised Master Label file (071995-AR-20191028) including the intended commercial name listed as an alternative brand name and a minor spelling correction.

We would appreciate if you could provide a status update, as we are eager to finalize this PRIA action.

Please feel free to contact me with any questions. Kindest Regards, Ona

**Ona Maune** | Regulatory Affairs | Bayer US Crop Science | Monsanto Company |  
Chemistry Federal Regulatory Affairs Manager | Lawn & Garden  
636.737.9577 office [ona.maune@bayer.com](mailto:ona.maune@bayer.com) Mail Zone FF4B

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**From:** MAUNE, ONA [AG/1005]  
**Sent:** Wednesday, November 6, 2019 10:15 AM  
**To:** Meadows, Sarah <Meadows.Sarah@epa.gov>  
**Cc:** Mellor, Nathan <Mellor.Nathan@epa.gov>; Schmid, Emily <Schmid.Emily@epa.gov>; NYANGULU, JAMES M [AG/1920] <james.m.nyangulu@monsanto.com>  
**Subject:** RE: EPA Reg No. 71995-AR

Good Morning Sarah,

As a follow-up to my 10/28 voicemail & email, I spoke with Nathan last week 10/30 regarding the revised CRP self-certification reflecting the new SAUE test conducted with 1.5 oz placebo (rice). His feedback from a cursory review was it would meet the CRP requirement and expected to be able to issue an amended memo. However, he was going to reach out to you directly for an official request (issue a 'bean') in order to move forward. If needed, I would be willing to process a Resubmission 8570-1 with the cover memo & CRP self-certification through the CDX portal/front desk; but Nathan didn't think that was necessary as it's not a data submission. Please advise how you would like to proceed.

Additionally, I had submitted a revised Master Label file (071995-AR-20191028) including the intended commercial name listed as an alternative brand name. The only other change was a spelling correction where 'advice' replaced 'advise'. No other changes were made to the Master Label (071995-AR-20190523) previously reviewed.

As mentioned, we are eager to complete this outstanding PRIA action and had previously communicated this was a top company priority.

Please reach out directly with any questions. Kindest Regards, Ona

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**From:** MAUNE, ONA [AG/1005]

**Sent:** Monday, October 28, 2019 8:01 PM

**To:** Meadows, Sarah <[Meadows.Sarah@epa.gov](mailto:Meadows.Sarah@epa.gov)>; Mellor, Nathan <[Mellor.Nathan@epa.gov](mailto:Mellor.Nathan@epa.gov)>

**Cc:** Schmid, Emily <[Schmid.Emily@epa.gov](mailto:Schmid.Emily@epa.gov)>; NYANGULU, JAMES M [AG/1920] <[james.m.nyangulu@monsanto.com](mailto:james.m.nyangulu@monsanto.com)>

**Subject:** FW: EPA Reg No. 71995-AR

Dear Sarah and Nathan,

In response to the CRP review letter (attached), I followed up directly with Nathan to obtain feedback regarding the unexpected decision and he shared the CRP committee was not comfortable with the Senior Adult Use Effectiveness (SAUE) conducted without 1.5 oz placebo; but had accepted the Child-Resistant Effectiveness (CRE). Upon further research in our archives, I discovered a lengthy history of communications between the Agency (including Dr. Rosalind Gross and Jim Tompkins), Monsanto Company and the testing laboratory. Nathan and I discussed this information, including the fact final study reports had been submitted and reviewed by the Agency under a separate registration (EPA# 524-535); which the CRP committee was unaware of during their review meeting. He advised, if I could locate the MRID#s, a possible path forward would be to simply update the Data Matrix to cite these studies already reviewed by the Agency for this pending PRIA action. Unfortunately, I reached out to Banza Djapao, who was unable to locate MRID#s for these studies.

Consequently, we contracted a revised Senior Adult Use Effectiveness (SAUE) test at National Child Resistant Testing, Inc. utilizing the same 1.5oz pouch containing placebo (rice). The study conclusion was one hundred adults (100%) were able to use a scissors to successfully open the sample pouches in both the 5-minute and 1-minutes test periods. Therefore Monsanto Company Lawn & Garden Products would like to submit a revised CRP certification reflecting the updated SAUE test conducted with placebo (rice) for Nathan's review and fulfillment of the CRP requirements per 40 CFR 157.2 and 157.34. Please find the cover memo and revised Child-Resistant Packaging Certification attached.

Additionally, I've attached the Master Label (file name 071995-AR-20191028) including the intended commercial name, Roundup EasyMix Dry Concentrate Weed & Grass Killer, listed as an alternative brand name. The only other change was a spelling correction where 'advice' replaced 'advise'. No other changes were made to the Master Label previously reviewed (file name: 071995-AR-20190523).

We are eager to complete this outstanding PRIA R300 action (EPA. Reg. No. 71995-AR, RD 1870 Herbicide- Decision 545751), and believe the revised CRP self-certification will fulfill the outstanding requirement. Please contact me directly with any questions.

Kindest Regards, Ona

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**From:** Meadows, Sarah <[Meadows.Sarah@epa.gov](mailto:Meadows.Sarah@epa.gov)>  
**Sent:** Thursday, July 25, 2019 7:38 AM  
**To:** MAUNE, ONA [AG/1005] <[ona.maune@bayer.com](mailto:ona.maune@bayer.com)>  
**Cc:** Mellor, Nathan <[Mellor.Nathan@epa.gov](mailto:Mellor.Nathan@epa.gov)>; Schmid, Emily <[Schmid.Emily@epa.gov](mailto:Schmid.Emily@epa.gov)>  
**Subject:** RE: EPA Reg No. 71995-AR

Hi, Ona, I received the review of your CRP submission for this proposed product this morning. Unfortunately the data you submitted was not sufficient to meet the CRP requirement. Please see the attached review for details.

Feel free to contact me or Nate to discuss.

Thanks,

Sarah

Sarah True Meadows, PhD  
US Environmental Protection Agency  
Office of Pesticide Programs  
Registration Division – Herbicide Branch  
(703) 347-0505  
[meadows.sarah@epa.gov](mailto:meadows.sarah@epa.gov)

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**From:** MAUNE, ONA [AG/1005] <[ona.maune@bayer.com](mailto:ona.maune@bayer.com)>  
**Sent:** Tuesday, July 23, 2019 1:56 PM  
**To:** Meadows, Sarah <[Meadows.Sarah@epa.gov](mailto:Meadows.Sarah@epa.gov)>  
**Cc:** [james.m.nyangulu@monsanto.com](mailto:james.m.nyangulu@monsanto.com)  
**Subject:** RE: EPA Reg No. 71995-AR

Good Afternoon Sarah,  
Thanks so much for following up with Nate directly and your assistance on getting this action finalized.

Kindest Regards, Ona

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**From:** Meadows, Sarah <[Meadows.Sarah@epa.gov](mailto:Meadows.Sarah@epa.gov)>  
**Sent:** Tuesday, July 23, 2019 12:50 PM  
**To:** MAUNE, ONA [AG/1005] <[ona.maune@bayer.com](mailto:ona.maune@bayer.com)>  
**Subject:** RE: EPA Reg No. 71995-AR

Hi, Ona. I just checked with Nate. I should have the CRP review by next week at the latest. As soon as I get it, I'll send the letter and label to the PM for their stamp and

Thanks,

Sarah

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**From:** MAUNE, ONA [AG/1005] <[ona.maune@bayer.com](mailto:ona.maune@bayer.com)>  
**Sent:** Tuesday, June 25, 2019 4:54 PM  
**To:** Mellor, Nathan <[Mellor.Nathan@epa.gov](mailto:Mellor.Nathan@epa.gov)>  
**Cc:** Meadows, Sarah <[Meadows.Sarah@epa.gov](mailto:Meadows.Sarah@epa.gov)>; [james.m.nyangulu@monsanto.com](mailto:james.m.nyangulu@monsanto.com)  
**Subject:** RE: EPA Reg No. 71995-AR  
**Importance:** High

Good Afternoon Nate,

Thanks for providing feedback and additional clarification regarding the CRP certification requirements. Per our discussion this morning, I've reviewed the acute oral and inhalation testing for this product. The results of the inhalation testing conducted (in which the granular test product was ground and sieved prior to dilution with 50% water) are within the requirements of 40 CFR 157.22 (3) and fall within the residential use criterion 40 CFR 157.22 (6)(b). Therefore, Monsanto Company Lawn & Garden Products is submitting a revised Child-Resistant Packaging (CRP) Certification letter per 40 CFR 157.34, as outlined on OPP's website and your note below.

Per our discussion this morning, you expected that you would be able to review this revised CRP certification by Thursday June 27<sup>th</sup>. We are trying to finalize this PRIA R300 action with Team 25, who have completed all of their reviews with the exception of this CRP certification (copying Sarah Meadows).

Thanks in advance for your assistance. Please call me directly with any questions.

Kindest Regards, Ona

*Ona Maune*  
Lawn & Garden Regulatory Affairs Manager

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**From:** Mellor, Nathan <[Mellor.Nathan@epa.gov](mailto:Mellor.Nathan@epa.gov)>  
**Sent:** Wednesday, June 19, 2019 12:45 PM  
**To:** [ona.maune@bayer.com](mailto:ona.maune@bayer.com)  
**Subject:** EPA Reg No. 71995-AR

Hello Ona,

I am reviewing the CRP certification. As written it is not acceptable. Below the signature of this email you find the information on certification from the OPP website on CRP. It can also be reviewed [here](#). Please review it and send a new certification letter to me directly or [ChildResistantPackaging@epa.gov](mailto:ChildResistantPackaging@epa.gov).

Thank you  
Nate

Nathan Mellor  
Biologist  
Fungicide Herbicide Branch  
Registration Division  
Office of Pesticide Programs  
(703) 347-8562

**The certification letter needs to include:**

- The product name and EPA registration number.
- State whether CRP is voluntary or required for the product.
- Identify which package is associated with the CRP test data:

- A description of the package tested including a photograph of the package (including closure model and size, material specification, package color, Manufacturer, ASTM classification, size package tested with, and fill volumes).
- The name of the testing firm.
- If you are employing any bridging rationales to cover certain packaging configurations, please explain.
- For the SAUE (see checklist below for 16 CFR 1700.20 requirements):
  - The directions on the package used for Senior Adult Use Effectiveness (SAUE) Testing along with any additional directions provided to the Seniors during SAUE Testing.
  - The number of Seniors tested.
  - Percent able to open the package after the initial 5 minutes.
  - Percent able to open the package in the next one-minute trial.
- For the Child-Resistant Effectiveness (CRE)(see checklist below for 16 CFR 1700.20 requirements):
  - The number of children tested.
  - The number of failures.
  - For unit dose packaging:
    - Define the number of units that represent a child failure.
    - The number of units a child receives at the beginning of the test.
- **The CRP certification statement:**  
 I certify that the packaging used for this product meets the standards of 40 CFR 157.32 including the revised standards in 16 CFR 1700.15(b) when tested by the revised testing procedures in 16 CFR 1700.20 as published in 60 FR 37710 (July 21, 1995).
- Please sign and date the certification and place on company letterhead (including the registrant name and address and the title and signature of company official).

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